

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

Bonnie Laderbush
and George Laderbush

v.

Civil No. 20-cv-62-JD
Opinion No. 2020 DNH 096

Ethicon, Inc., and
Johnson & Johnson

O R D E R

Defendants Ethicon, Inc., and Johnson & Johnson (collectively, "Ethicon") move to exclude the testimony of Dr. Uwe Klinge, M.D., under [Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 \(1993\)](#). Doc. 54. Ethicon challenges Dr. Klinge's opinion on two matters. It asserts that his opinion about alternative designs should be excluded as unreliable. Ethicon also challenges the reliability of Dr. Klinge's opinion that the "Prolene" mesh used in the construction of its "TVT Exact" product is defective due to fraying and particle loss. The plaintiffs, Bonnie and George Laderbush, object to the exclusion of Dr. Klinge's opinion about alternative designs, but they will not introduce Dr. Klinge's opinion about fraying and particle loss. Ethicon did not file a reply.

Standard of Review

To testify as an expert, a witness must be qualified to do so "by knowledge, skill, experience, training, or education."

[Fed. R. Evid. 702](#). A qualified expert witness “may testify in the form of an opinion or otherwise” if the witness’s “scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;” if “the testimony is based on sufficient facts or data;” if “the testimony is the product of reliable principles and methods;” and if “the expert has reliably applied the principles and methods to the facts of the case.” Id. Once the expert’s qualifications are established, the opinion is shown to be relevant, and the bases for the opinion are both sufficient and reliable, “the credibility and weight of the expert’s opinion [are] for the factfinder.” [United States v. Jordan](#), 813 F.3d 442, 446 (1st Cir. 2016); see also [Daubert](#), 509 U.S. at 597.

Background

The Laderbushes’ products liability case revolves around the safety of an implant called “TVT Exact,” which is marketed by Ethicon as a treatment for stress urinary incontinence. TVT Exact is constructed with a synthetic polypropylene mesh known as “Prolene”. The Laderbushes allege that the Prolene mesh used in TVT Exact is not suitable for use in treating stress urinary incontinence.

In his expert report, Dr. Uwe Klinge opined that the relatively large surface area of the Prolene mesh increases post-implant inflammation, which causes unnecessary complications for implant recipients. Dr. Klinge asserted that a mesh design with a smaller surface area would be sufficient to treat stress urinary incontinence while reducing the risk of inflammation and foreign body response. Dr. Klinge also opined that the distance between the fibers of the mesh (i.e., its "pore size") is smaller in the Prolene mesh than is necessary, which increases the risk of injury to implant recipients.

Further, Dr. Klinge explained that the Prolene mesh used in TVT Exact was designed in the 1970s. He asserted that in the late 1990s and early 2000s, synthetic meshes with a smaller surface area and a larger pore size were developed and marketed by Ethicon. Dr. Klinge noted the "Ultrapro" mesh as an example of a mesh with a smaller surface and larger pore size.

Discussion

A. Alternative Designs

Ethicon argues that Dr. Klinge's opinion that Ultrapro is a safer alternative to Prolene should be excluded as unreliable. Ethicon argues that Dr. Klinge's expert report in this case "is essentially identical" to Dr. Klinge's expert report about alternative designs that was excluded as unreliable in a similar

mesh products liability case, [Bellew v. Ethicon, Inc.](#), No. 2:13-cv-22473, 2014 WL 12685965 (S.D. W.Va. Nov. 20, 2014). Ethicon contends that, in that case, the court found that Dr. Klinge failed to cite peer-reviewed studies to support his opinion about alternative designs, which rendered it unreliable.

The Laderbushes respond that the expert opinion excluded in [Bellew](#) and referenced by Ethicon is different from the opinion Dr. Klinge produced in this case. While the opinion excluded in [Bellew](#) did address alternative designs to Prolene, the portion excluded related only to the use of a design known as "PVDF" as an alternative, while the opinion relied upon by the Laderbushes in this case suggests Ultrapro as an alternative. The Laderbushes argue that Dr. Klinge's current report rectifies the issue that resulted in its exclusion in [Bellew](#). The Laderbushes assert that Dr. Klinge provides a detailed and scientifically-based explanation about the advantages of Ultrapro over Prolene.

[Bellew](#) is distinguishable from this case. In [Bellew](#), the court excluded Dr. Klinge's opinion about a specific alternative design, namely, PVDF. [Bellew](#), 2014 WL 12685965 at *9. The opinion about that design was excluded because Dr. Klinge failed to explain why PVDF was a superior alternative or support his opinion with any reliable scientific basis, such as peer-reviewed studies. [Id.](#) By contrast, in this case, Dr. Klinge's basis for asserting that Ultrapro is a superior alternative

design to Prolene is explained. He notes that Ultrapro has a smaller surface area and larger pores. His opinion that meshes with smaller surface areas and larger pores are preferable to Prolene is supported by a comprehensive discussion and references to his research, experience, and peer-reviewed studies.

Ethicon also contends that Dr. Klinge's opinion about alternative designs should be excluded because, in his deposition, Dr. Klinge could not identify any mesh that was "appropriate for use in the pelvic floor for the repair of pelvic organ prolapse" or any mesh with benefits that exceed their risks. Doc. 55 at 3. The Laderbushes respond, arguing that Ethcion mischaracterizes Dr. Klinge's position. The Laderbushes assert that Dr. Klinge merely acknowledged that the Ultrapro mesh is not perfect.

Ethicon misunderstands Dr. Klinge's deposition testimony. Dr. Klinge did not say that there are no meshes that are suitable for use in the treatment of pelvic organ prolapse. Rather, in the portion of the deposition identified by Ethicon, Dr. Klinge responded that Ethicon's question "doesn't make any sense" because it is "a general statement." Doc. 55-3 at 43, 48. Just prior to this question and response, Dr. Klinge had explained that he does not think there is any single mesh device that is suitable for treatment of every disease in the pelvic

floor. Id. ("There is never one device for all diseases in the pelvic floor. No, it's not done. It has to be very carefully designed for the specific purpose."). The court denies Ethicon's motion to exclude Dr. Klinge's opinion about Ultrapro as an alternative design.

B. Fraying and Particle Loss

Ethicon also argues that Dr. Klinge should be prohibited from testifying about "fraying and particle loss." Doc. 55 at 4. The Laderbushes respond that they will not ask Dr. Klinge to opine about fraying and particle loss. Accordingly, this ground for exclusion is denied as moot.

Conclusion

Ethicon's motion to exclude the testimony of Dr. Uwe Klinge (doc. no. 54) is denied in part and denied as moot in part. The motion is denied as to Dr. Klinge's opinion regarding Ultrapro as an alternative design. It is denied as moot as to Dr. Klinge's opinion regarding fraying and particle loss.

SO ORDERED.


Joseph A. DiClerico, Jr.
United States District Judge

June 4, 2020
cc: Counsel of Record.